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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,526	11/21/2001	Yasushi Shigemori	032735-004	9938

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,526	Applicant(s) SHIGEMORI ET AL.	
	Examiner Teresa E Strzelecka	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2004 and 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-18 is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>17062003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to amendments filed July 17 and December 22, 2003.

Claims 1-10 were previously pending. Applicants cancelled claims 1-10 and added new claims 11-20.

2. Applicants' amendments overcame the following: objection to claims 1-9; rejection of claims 1-8 and 10 under 35 U.S.C. 112, second paragraph; rejection of claims 9 and 10 under 35 U.S.C. 102(b) over Pati et al. (U.S. Patent 6,200,812); rejection of claims 9 and 10 under 35 U.S.C. 102(b) over Pati et al. (U.S. Patent 6,074,853); rejection of claims 9 and 10 under 35 U.S.C. 102(e) over Pati et al. (U.S. Patent 6,200,812); rejection of claims 9 and 10 under 35 U.S.C. 102(b) over Kigawa et al. (U.S. Patent 6,335,164).

3. Applicants' amendments to the specification overcame the objections given in the previous office action.

4. Regarding the IDS submitted September 9, 2002, there was only one-page 1449 submitted, which was acknowledged by the examiner. The sheet was numbered 1_of_1, therefore it is not clear how it could have contained another page, as stated by Applicants.

5. Claims 11-20 are pending and will be examined.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on June 17, 2003 was filed after the mailing date of the non-final office action on December 20, 2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pati et al. (U.S. Patent No. 5,948,653 A).

Regarding claims 19 and 20, Pati et al. teach a kit comprising oligonucleotide DNA probes and recombinases (= homologous recombination proteins) (col. 35, lines 58-62). Pati et al. Also teach reagents for removing the recombinase: proteinases, such as proteinase K, detergents, such as SDS, and a composition containing phenol-chloroform-isoamyl alcohol (col. 29, lines 55-60).

9. Claims 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Shigemori et al. (U.S. Patent No. 6,541,226 B1; cited in the IDS).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e).

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This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 19 and 20, Shigemori et al. teach a kit comprising a homologous recombination protein (col. 2, lines 39-56). Shigemori et al. teach oligonucleotides which hybridize to double-stranded DNA (= oligonucleotide probe) (col. 2, lines 14-20, 28-34; Fig. 17). Shigemori et al. teach deproteinization of the DNA-RecA complex, using SDS or proteinase K (= a reagent for removing the homologous recombination protein) (Fig. 17; col. 7, lines 25-31).

Allowable Subject Matter

10. No references were found teaching or suggesting claims 11-18. The closest prior art reference, Erikson et al. (US 2003/0113716 A1), teaches detection of nucleic acid sequences by formation of nucleic acid triplexes or quadruplexes in the presence of homologous recombination proteins (see, for example, page 2, [0029], [0036]; page 4, [0071]-[0075]), but does not teach removal of the homologous recombination protein or releasing the probe from triple-stranded DNA.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the

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date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS
February 24, 2004



JEFFREY FREDMAN
PRIMARY EXAMINER